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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,840	08/22/2003	Cara A. Pellegrini	08576.0012-01	8135

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,840	PELLEGRINI ET AL.	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-11,30-32 and 34-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-29 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 03/05/2007 to Office Action mailed on 10/04/2006 is acknowledged.

Election/Restrictions

Applicant's election of Group II (claims 12-29 and 33) with traverse is acknowledged. Applicant argues that restriction between the claims is not proper because a search of all claims would not impose an undue burden. Applicant believes that there is extensive overlap in subject matter between the claims and therefore all claims should be examined together. Although, all Groups have been classified in the same class and subclass a search in the non-patent literature would require a different field of search for each Group of claims. Prior art that may be applied to one Group of claims will not necessarily be applicable to another Group of claims. For the foregoing reasons the restriction requirement is proper and is made final.

Status of Claims

Claims 1-11, 30-32, and 34-39 are withdrawn as being directed to non-elected claims. Therefore, claims 12-29 and 33 are pending examination for patentability.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 reads, "administering ... a therapeutically effective amount of tizanidine" and further reads, "wherein the tizandine tablet is from a container". It is unclear if the claim is limited to a tablet form or tizanidine in any formulation to be administered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-29 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Apgar (*Approval of Tizanidine for Treatment of Spasticity*, American family Physician, Published 02/01/1998).

Apgar teaches, "In its oral form, tizanidine is rapidly and completely absorbed, especially when taken with food. It is excreted in the urine and feces. Since the absorption is increased when it is taken with food, taking the regularly with meals can increase the consistency of both therapeutic and adverse effects." (See page 2, paragraph 2). Apagar further teaches that the typical dosage is one 4-mg tablet followed by an increase by one-half tablet every three days until a dosing schedule of three times daily can be achieved. (See page 2, paragraph 3). This would necessarily include dosing up to 12 mg and including 8 mg. In regards to the limitation of a label the label

does not distinguish the instant method over the prior art since addition of printed matter to existing product will not distinguish the invention from the prior art in terms of patentability if the printed matter is not functionally related to the product. As upheld by the courts, "[T]he critical question is whether there exits any new and unobvious functional relationship between the printed matter and substrate". In re Gulack, 703 F. 2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983). In the instant case, the examiner points out that the printed instructions do not render a new and unobvious functional relationship between the printed matter and the substrate. Applicant is claimed a method of use of a well known product, i.e. tizandine, wherein the purportedly novelty is in the instructions of using the product. However, the examiner points out that the use of tizanidine with the consumption of food to increase absorbency and consitancy of therapeutic effect is well known as evidenced by Apgar. Thus the addition of printed instructions on or near the product does not render the instant method patentable. In regards to the extent of absorption and Cmax values it is the examiner position that the instantly claimed method steps are not distinguishable from the prior art and therefore the extent of absorption and Cmax values would necessarily be the same since the same dose is administered. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco

Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." (See MPEP 2105). If applicant contends the Cmax is not inherent then it is applicants burden to provide evidence to the contrary. For the foregoing reasons the instantly claimed method is anticipated by the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

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